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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/865,989 | 05/25/2001 | Jean-Louis Dasseux | 9196-019-999 | 6407 |

24341 7590 07/11/2003

Pennie & Edmonds, LLP
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Palo Alto, CA 94304

EXAMINER

RUSSEL, JEFFREY E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,989

Applicant(s)

DASSEUX ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claims 84-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 84-86 are dependent upon canceled claim 1.
2. Claims 76-103 are objected to because of the following informalities: It is redundant to state in claim 76 that X_1 can be Pro or D-pro when lines 24-25 of the claim state that at least one residue of the peptide or peptide analogue can be a D-enantiomeric residue. Appropriate correction is required.
3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
4. Claims 76-103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,265,377. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '377 patent anticipate the instant claims. The '377 patent claims ApoA-I agonist compounds having the same structure and same amino acid sequence in which residue X_1 can be D-proline. The agonist compounds are present in the same compositions and are used in the same therapeutic methods claimed in the instant application.

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5. Claims 76-103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,037,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '323 patent anticipate the instant claims. The '323 patent claims ApoA-I agonist compounds having the same structure and same amino acid sequence in which residue X₁ can be D-proline. The agonist compounds are present in the same compositions and are used in the same therapeutic methods claimed in the instant application.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 76, 78, 83, 92, 94, and 95 are rejected under 35 U.S.C. 102(e) as being anticipated by Dasseux et al (U.S. Patent No. 6,004,925). Dasseux et al '925 teaches peptides having SEQ ID NOS 87, 96, 100, 107, and 174 (see Table X at columns 67-70) which are comprised entirely of D-amino acids and are 22 amino acids in length, and which form amphipathic alpha-helices. In the LCAT Activation Assay (see, e.g., column 63, lines 41-48), the peptides are combined with lipids, e.g., in the form of micelles and SUVs. Because Applicants' claims permit the substitution of amino acids in formula (I) with non-identical D-enantiomeric residues, the peptides of Dasseux et al '925 anticipate the instant claims.

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8. Claims 76, 78, 83, 92, 94, and 95 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 99/16459. The WO Patent Application '459 is equivalent to Dasseux et al '925 applied above, and anticipates Applicants' claims for the same reasons set forth above, albeit under a different section of 35 U.S.C. 102.

9. Applicants' response filed June 10, 2003 has overcome the objections and rejections set forth in the Office action mailed February 10, 2003.

The examiner interprets claim 76, lines 24-25, as indicating that any and all residues in the peptide or peptide analogue can be replaced with either an identical or a non-identical D-enantiomeric residue. This interpretation is necessary in order to give meaning to dependent claim 77, which otherwise would be redundant and would not further limit the scope of the independent claim. If the examiner's interpretation of the claim scope is incorrect, Applicants are required to provide their interpretation of the claim language in the response to this Office action. The rejections over Dasseux et al '925 and over the WO Patent Application 99/16459 could be overcome by amending claim 76 to require that any substitutions with a D-enantiomeric residue are with the identical D-enantiomeric residue.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

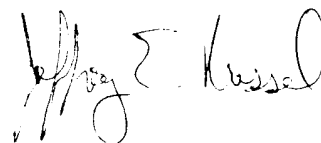
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 10, 2003